REMARKS

Claims 1, 6-8, 11 and 12 have been amended.

Rejection of Claims 7, 11 and 12 Under 35 U.S.C. § 112, Second Paragraph

Claims 7, 11 and 12 have been rejected under 35 U.S.C. § 112, second paragraph, as being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

Claim 7 is said to be vague and indefinite in reciting "suitable" control animals. Claim 7 has been amended, and as amended, does not recite the term "suitable."

Claim 11 is said to be vague and indefinite in that the metes and bounds of the phrase ". . . wherein observing fewer cells or slower growth of cells in said test animals compared to cells or growth of cells. . ." are said to be unclear. Claim 11 has been amended as the Examiner suggested, to clarify the meaning of the claim.

Claim 12 is said to be vague and indefinite in the reciting "the control animals" where it is said there is no antecedent basis for this phrase. Claim 12 has been amended as the Examiner suggested, to delete the definite article from this phrase.

Rejection of Claims 1, 2, 6, 7, 8 and 9 Under 35 U.S.C. § 103(a)

Claims 1, 2, 6, 7, 8 and 9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bostian *et al.* (WO 96/40979; 19 December 1996) in view of Setterstrom *et al.* (US 6,309,669 B1).

Bostian *et al.* describe methods in which endogenous genes of microbes are genetically altered so that their expression can be regulated. The genes are either pathogenesis genes or essential genes to be tested for their effect on pathogenesis of the microbe, when the gene is regulated to produce its gene product following infection of an animal with the microbe bearing the genetic alteration.

Setterstrom *et al.* describe experiments in which groups of animals were subjected to different treatment regimens for antibiotic therapy or vaccine testing. In each case, a group of animals was left untreated as a control group for comparison with the treated groups.

Claims 1, 6, 7 and 8 have been amended to make clear that the biomolecule of the claims has the property of binding to a target cell component. The gene products of the pathogenesis genes and essential genes of Bostian *et al.* are not described as having this property, and nothing in either of the cited references or in the combination suggests choosing a gene having this property, to be introduced into a pathogen, and regulated to produce its gene product. Therefore, the methods of Claims 1, 2, 6, 7, 8 and 9 are not rendered obvious by the combination of the teachings of Bostian *et al.* and Setterstrom *et al.*

CONCLUSION

The Examiner is respectfully requested to consider the above amendments and remarks, and to withdraw the rejections. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Carol A. Egner

Carol A. Egner
Registration No. 38,866
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Dated: September 23, 2002

MARKED UP VERSION OF AMENDMENTS

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

1. (Three Times Amended) A method for determining whether a biomolecule inhibits infection by a pathogen cell, comprising the steps of:

a) introducing into a test animal and into a control animal a pathogen cell comprising an exogenous regulable gene encoding the biomolecule, wherein the biomolecule binds a target component of the pathogen cell;

b) regulating expression of the exogenous gene to produce the biomolecule in the cell in the test animal but not in the cell in the control animal; and

c) monitoring said test and control animals for signs of infection;

whereby observing fewer or less severe signs of infection in said test animal compared to signs of infection in the control animal indicates that the biomolecule inhibits infection by the pathogen cell.

6. (Twice Amended) A method for determining whether a biomolecule inhibits infection by a pathogen cell, comprising the steps of:

a) constructing a pathogen cell comprising an exogenous regulable gene encoding the biomolecule, wherein the biomolecule binds a target component of the pathogen cell;

b) introducing said pathogen cell into a test animal and a control animal;

c) regulating expression of the gene to produce the biomolecule in the pathogen cell in the test animal but not in the cell in the control animal; and

d) monitoring said test and control animals for signs of infection;

whereby observing fewer or less severe signs of infection in said test animal compared to signs of infection in the control animal indicates that the biomolecule inhibits infection by the pathogen cell.

7. (Three Times Amended) A method for determining whether a biomolecule is a biomolecular inhibitor of growth of cells, comprising:

a) introducing into one or more test animals and into one or more [suitable] control animals cells having a regulable gene encoding a biomolecule, wherein the biomolecule binds a target component of the cells;

b) regulating, in the test animals, expression of the gene to allow production of the biomolecule; and

c) monitoring said test animals for growth of the cells;

wherein observing fewer of the cells or a slower growth rate of the cells in said test animals compared to the number of the cells or growth rate of the cells in the control animals indicates that the biomolecule is a biomolecular inhibitor of growth of the cells.

8. (Three Times Amended) A method for assessing whether a biomolecule is a biomolecular inhibitor of growth of cells in a host mammal comprising:

a) constructing cells having a regulable gene encoding the biomolecule, wherein the biomolecule binds a target component of the cell;

b) introducing the cells into test animals and into control animals;

c) regulating, in the test animals, expression of the regulable gene to produce the biomolecule; and

d) monitoring the test animals and control animals for growth of the cells;

wherein observing less growth of the cells in the test animals than in the control animals indicates that the biomolecule is a biomolecular inhibitor of growth of the cells.

11. (Three Times Amended) A method for determining whether a target component of a cell is essential for growth of said cell in an animal, comprising:

a) in cells comprising a biomolecule and a target cell component, wherein the biomolecule is a biomolecular binder of the target cell component, and wherein a gene encoding the biomolecule is regulable, regulating expression of the gene to produce the biomolecule;

b) monitoring growth of the cells in culture relative to growth of control cells, whereby, if growth is decreased in the cells compared to growth of the control cells, then the biomolecule is a biomolecular inhibitor of growth of the cells;

c) introducing into one or more test animals cells in which growth can be decreased compared to the control cells as determined in step b);

d) regulating expression of the gene to produce the biomolecular inhibitor of growth in the introduced cells; and

e) monitoring said test animals for inhibition of the growth of the cells;

wherein observing fewer cells or slower growth of cells in said test animals compared to the number of cells or growth of cells, respectively, in the control animals indicates that the target component of said cell is essential for growth of said cell in an animal.

12. (Twice Amended) A method for identifying a biomolecular inhibitor of growth of cells, comprising:

a) in cells comprising a biomolecule and a target cell component, wherein the biomolecule is a biomolecular binder of the target cell component, and the gene encoding the biomolecule is regulable, regulating expression of the gene to allow production of the biomolecule;

b) monitoring growth of the cells in culture relative to growth of control cells, whereby, if growth is decreased in the cells compared to growth of the control cells, then the biomolecule is a biomolecular inhibitor of growth;

c) introducing into one or more test animals cells in which growth can be decreased compared to the control cells in step b);

d) regulating expression of the gene to allow production of the biomolecule in the introduced cells; and

e) monitoring said test animals for inhibition of the growth of the cells;

wherein observing fewer cells or slower growth of cells in said test animals compared to cells or growth of cells, respectively, in [the] control animals indicates that the biomolecule is a biomolecular inhibitor of growth of cells.